

REMARKS

I Disposition of Claims

Claims 1, 3, 9, 10, 12, and 13 remain pending. No claims are currently amended.

II Non-Obviousness

The Examiner has rejected Claims 1, 3, 9, 12, and 13 under 35 USC 103(a) as being obvious over Botich (US 5,407,431), in view of Ericson (US Pub 2001/0014996 A1) and Skakoon (US 4,804,368). However, as explained in Applicants' previous response, even if one having ordinary skill in the art were to combine various elements of these references in the manner suggested by the Examiner, there would be no way for such a person to predict the significant unexpected results obtained by the present invention. In particular, the roughened flange held by the flange insertion groove of the current invention allows for injection with much higher injection pressure than one could obtain with the manual injection disclosed by Botich. These unexpected results would overcome a *prima facie* showing of obviousness even if such a showing were present.

Notwithstanding the foregoing, the Examiner dismissed the Applicants' arguments of unexpected results. The Examiner believed that the Applicants had not demonstrated the criticality of the unexpected results. Accordingly, Applicants are provided a more detailed explanation of the criticality of these results.

One of the principle advantages of the apparatus of the claimed invention is the prevention of breakage of the syringe barrel when used with an injector for injection of contrast medium. This problem is discussed in the present specification at page 2, lines 13-25. The Applicants unexpectedly discovered that such breakage could be prevented by providing a roughening of the surface of the flange so as to place and position the flange of the syringe barrel in the proper position in the groove. See, specification at page 24, lines 1-5.

This criticality of this surprising effect is demonstrated in the Examples and Comparative Examples of the specification on pages 27-28. In particular, Table 1 shows the results obtained for three different roughened flanges in accordance with the presently claimed apparatus, while Table 2 shows results of the comparative examples without roughened flanges. It can be seen that both the injection rate and maximum pressure for the examples having roughened surfaces were significantly and unexpectedly increased relative to the examples without roughening on the flanges. Moreover, three continuous injections were provided using the examples provided with

roughened flanges, while various problems were experienced with the non-roughened flanges, including low injection rates, raises and deviations from the holder, and broken syringe barrels.

None of the cited art even suggests that there is a problem of breakage of the flange. As such, none of the prior art suggests any solution to the problem, much less that roughening the surface of the flange could be used to avoid this problem. Thus, nothing in the cited art would lead one having ordinary skill in the art to have expected the foregoing results. As such, these results are both significant and unexpected in the art. In view of these results, any *prima facie* showing of obviousness would be overcome. Therefore, the claims should be considered non-obvious and the rejection withdrawn.

CONCLUSION


In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 
Eric Ives
Registration No. 50,928
Agent of Record
Customer No. 20,995
(805) 547-5580